

DYNAMIC INTERFACE REPORT

STATIC AND FATIGUE FLEXO COMPRESSION ASSEMBLY RESISTANCE RESULTS: DENTAL IMPLANT DYNAMIC INTERFACE

WITH FINITE ELEMENTS.

ANALYZED MODEL:

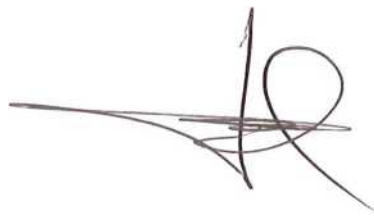
NOBEL BIO CARE REGULAR MULTI-UNIT ABUTMENT

STUDY DIRECTED TO THE ENTERPRISE: **TALLADIUM ESPAÑA, S.L.**

10/10/14

0. SIGNED SHEET:

Signed:



Report prepared by:

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1. OBJECTIVE

Objectives have been defined for the static trial and for dynamics or fatigue:

Static trial: Bearing in mind that 50 and 370 N values have been obtained for maximum bite force with the incisor teeth (Paphangkorakit and Osborn, 1997; Fontijn- Tekamp et al. , 2000; Regalo et al. , 2008). Between 50 and 200 N for maximum bite force with the canine teeth (Sinn et al., 1996; Fontijn-Tekamp et al. , 2000). Between 100 and 260 N for maximum bite force with the premolar teeth (Sinn et al., 1996; Fontijn-Tekamp et al., 2000). And between 60 and 645 N for maximum bite force with molar teeth (Sinn et al., 1996; Fontijn-Tekampo et al., 1998; Pereira-Cenci et al., 2007; Regalo et al., 2008). **The aim of this study is to demonstrate that the whole Nobel Biocare Brand Multi-Unit Regular Abutment Connection is higher than 700 N, so that it would be suitable for use in the preparation of dental prostheses for both front and back teeth.**

Fatigue trial: Bearing in mind that chewing force values of between 5 and 54 N have been obtained for incisor and canine teeth (Gay et al., 1994; Dan et al., 2003; Kohyama et al., 2004a, 2004b, 2005; Johnsen et al., 2007; Xu et al., 2008) and peak values between 50 and 284 N for premolars and molars (Morneburg Pröschel and, 2003; Kohyama et al., 2004a, 2004b; Johnsen et al., 2007). **The aim of this study is to demonstrate that the whole Nobel Biocare Brand Multi-Unit Regular Abutment Connection is higher than 350 N, so that it would be suitable for use in the preparation of dental prostheses for both front and back teeth.**

2. CONDUCTING THE TRIAL

2.1. Introduction

The present report presents the results for the flexo-compression static and fatigue simulation study, for a set of Dynamic Interface and dental implant of Multi-Unit Connection type Nobel Biocare Brand Regular Abutment The Multi-Unit model implemented uses a M1.4 screw, which is the most crucial of all those used.

For the report, the ISO 14801:2007 standard "Dentistry–Implants–Dynamic fatigue test for endosseous dental implants" was used.

The trial was performed by simulating the assembly with finite element software.

The results obtained in the report are theoretical, and confirmed in point 3 of the trial validation through the comparison of this system with the results of the analysis done by the Instituto de Biomecánica de Valencia (IBV) (Institute of Biomechanics in Valencia).

2.2. Company

The report was made upon request by the company:

<i>Name</i>	Talladium España, S.L.
<i>Address:</i>	Av. Bondel 54, 3o. 25002 Lleida (Spain)
<i>Telephone</i>	(+34) 973 289 580
<i>Email address</i>	info@talladiumes.com

2.3. Regulations

The regulation taken into account for carrying out the study is the following:

- ISO 14801:2007 "Dentistry-Implants-Dynamic fatigue test for endosseous dental implants."

– ISO 1942 "Dental vocabulary."

2.4. Material Used

Below is the list of medical products used to carry out the static and fatigue resistance trial:

2.4.1. Components Used

Component	Reference	Description	Material	Measurements
Dynamic Interface	IND3C041/TIA	Regular Abutment Multi-Unit Dynamic Interface	Ti Al6 V4	Ø5.3mm
Screw	TPDH14L39	Dynamic Pillar Screw@3.0	Ti Al6 V4	Ø2.4mm L 0.15in
Implant	Nobel Biocare Multi-Unit	Nobel Biocare Dental Implant RP Multi-unit	Titanium	Ø 4.8 mm L 13mm

2.4.2. Properties of the Material

Titanium 6Al-4V Grade5	
Model Type	Isotropic, lineal elastic
Elastic Limit	7.9e+008 N/m²
Tensile Stress Limit	8.6e+008 N/m²
Elastic Modulus/Toughness	1.138e+011 N/m²
Density	4430 kg/m³
Shear Modulus	4.4e+010 N/m²
Thermal Expansion Coefficient	9e-006 /Kelvin

2.5. Simulation Method

The geometric arrangement of the simulation is described in ISO 14801:2007 in paragraph 5, figure 2.

Figure 1 shows the geometric arrangement of the elements tested according to ISO 14801:2007.

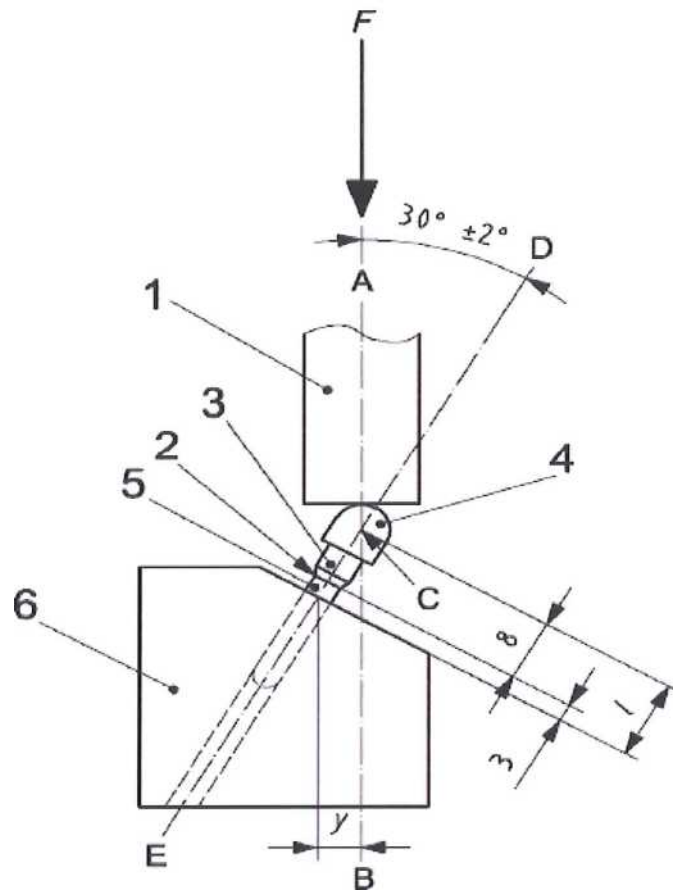


Figure 1 - Diagram of the trial installation

Heading

1. Charging device
2. Nominal bone level
3. Connection part
4. Hemispheric load member
5. Dental implant body
6. Specimen holder
- F. Loading force
- C. Loading center

The assembly of the simulation components can be seen below.

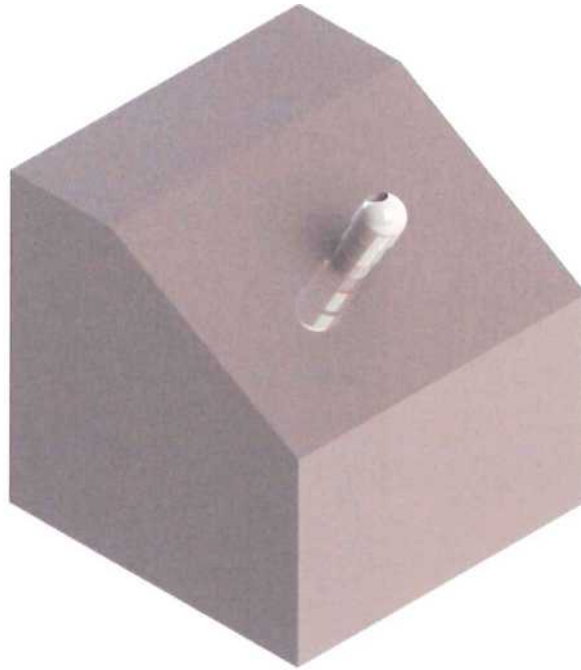


Figure 2: Isometric View



Figure 3: Solid Lateral View

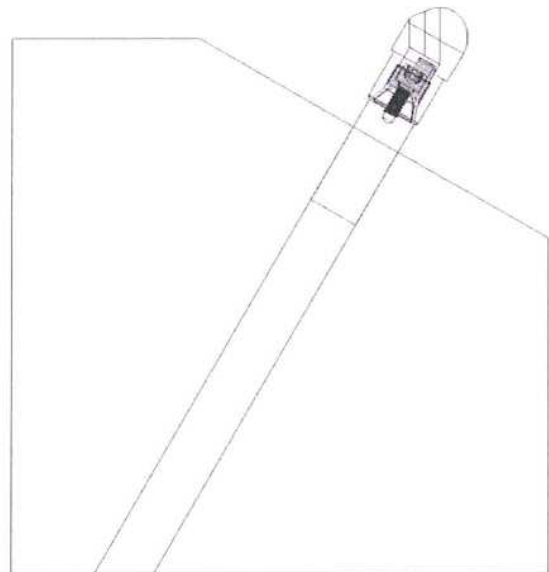


Figure 4: Lateral Wired View

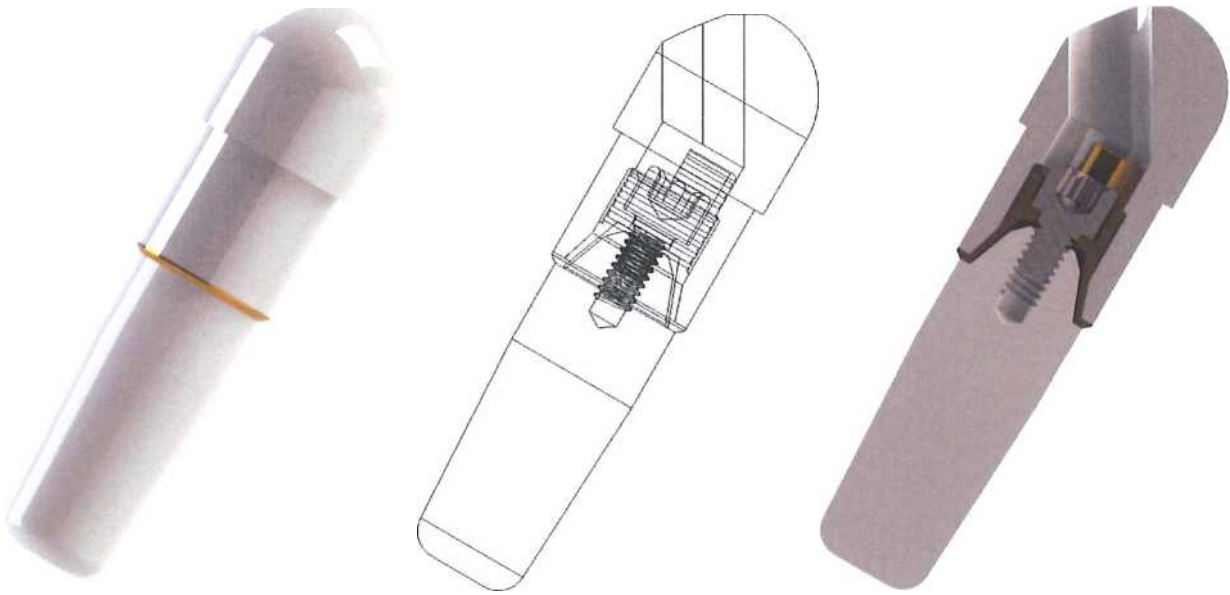


Figure 5: Implant-Interface -Screw Assembly

2.6. Applied Loads

The loads applied to the assembly were developed as previously described in figure 1. Figure 6 shows the assembly with the load and the application site.



Figure 6: Load applied to the assembly

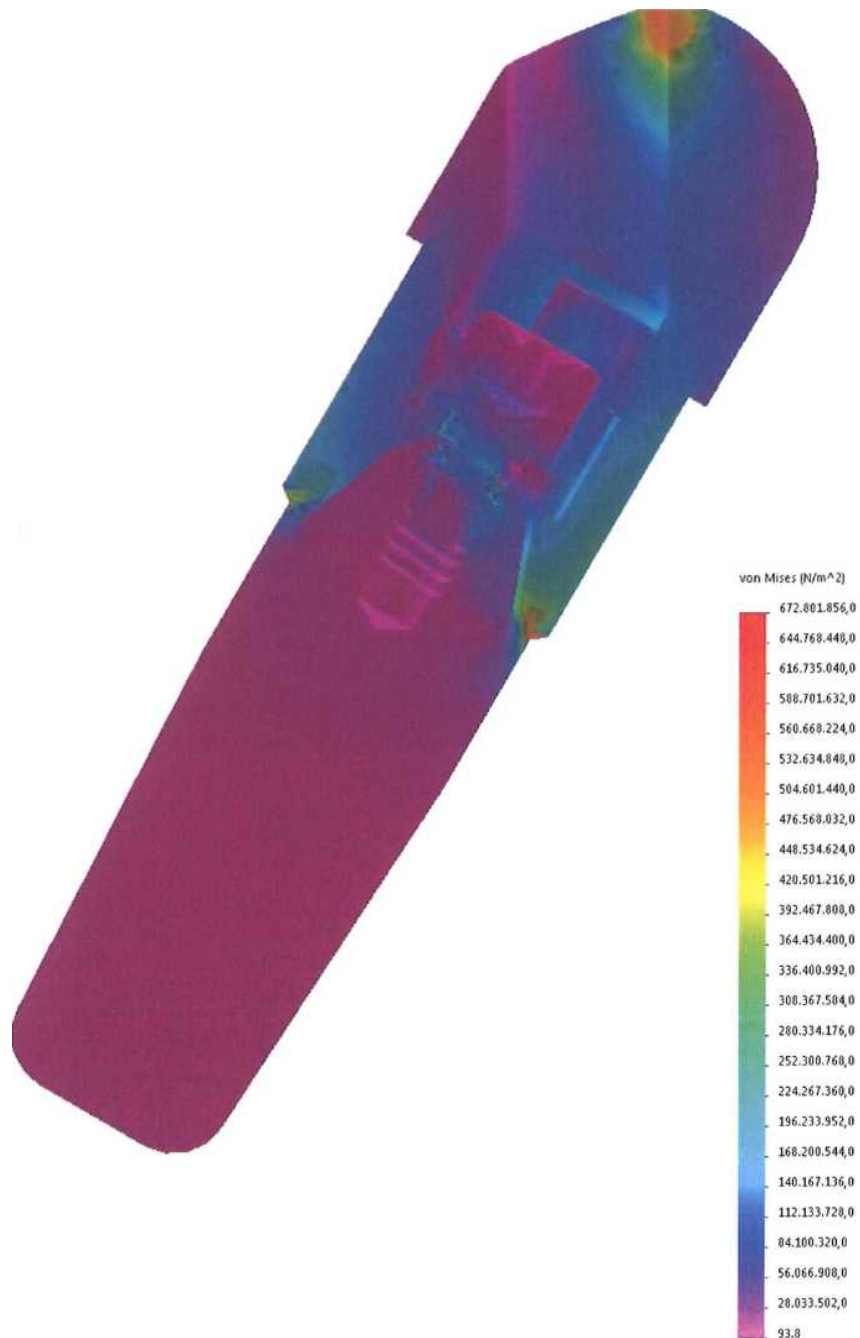
2.7. Static Resistance Results

Static resistance to flexo-compression was simulated for the implant and interface with the aim of determining the load in the elasticity limit and fracture load. The environmental conditions of the simulation are those stated in ISO 14801:2007.

Assembly	Yield Strength Limit (N)	Fracture Strength (N)
Nobel Biocare Multi-Unit RP	774	882

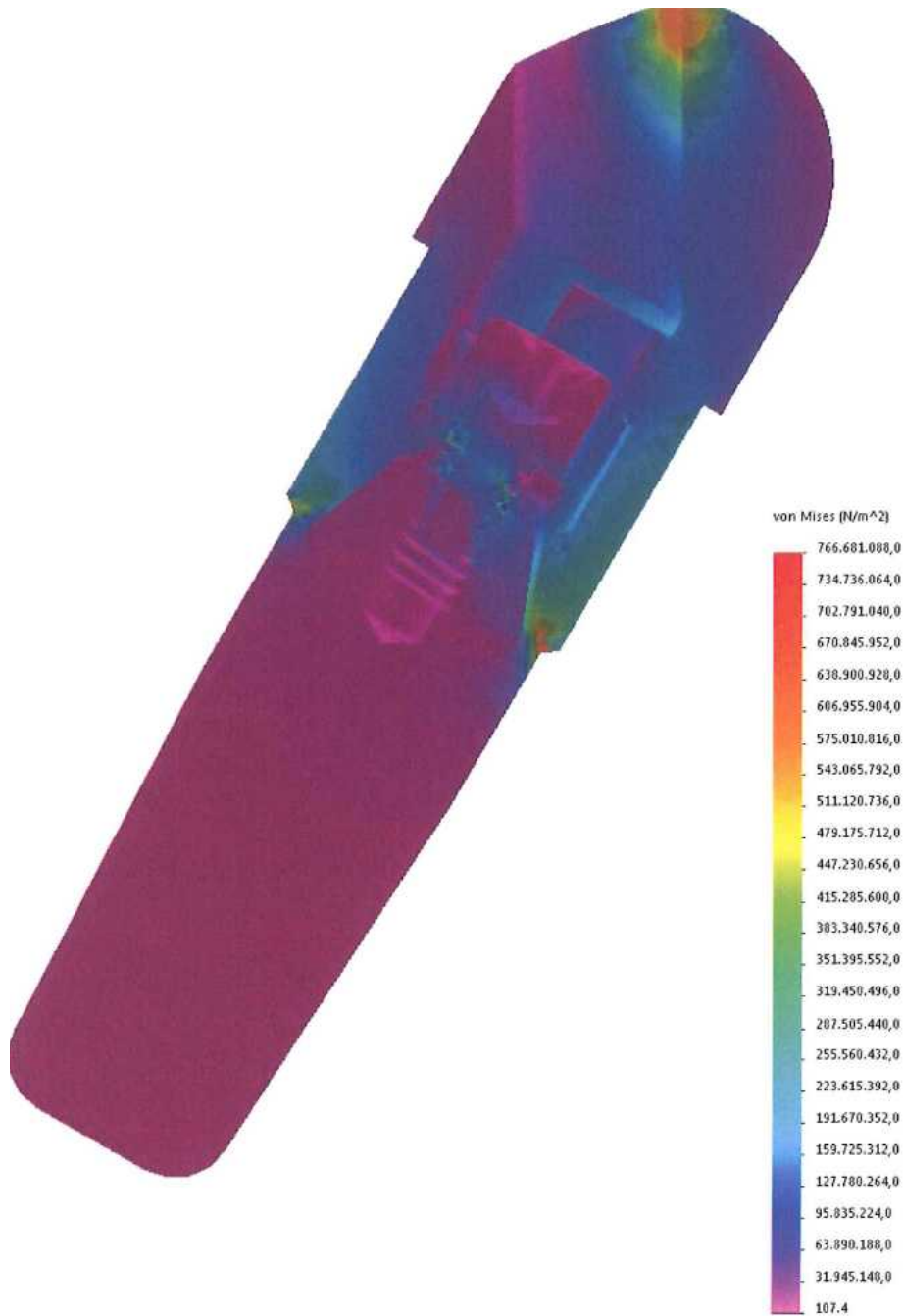
2.7.1. Elasticity Stress Limits.

The elastic limit is reached at **774 N**. The critical areas of the assembly are those shown in a greenish and reddish tone, which is where the load is applied and the connection area between the 3.0 Dynamic Interface and the implant.



2.7.2. Fracture Stress.

The breaking limit is reached at a load of **882 N**. When the load of 882 N is applied, the assembly fails to work and results in a fracture.



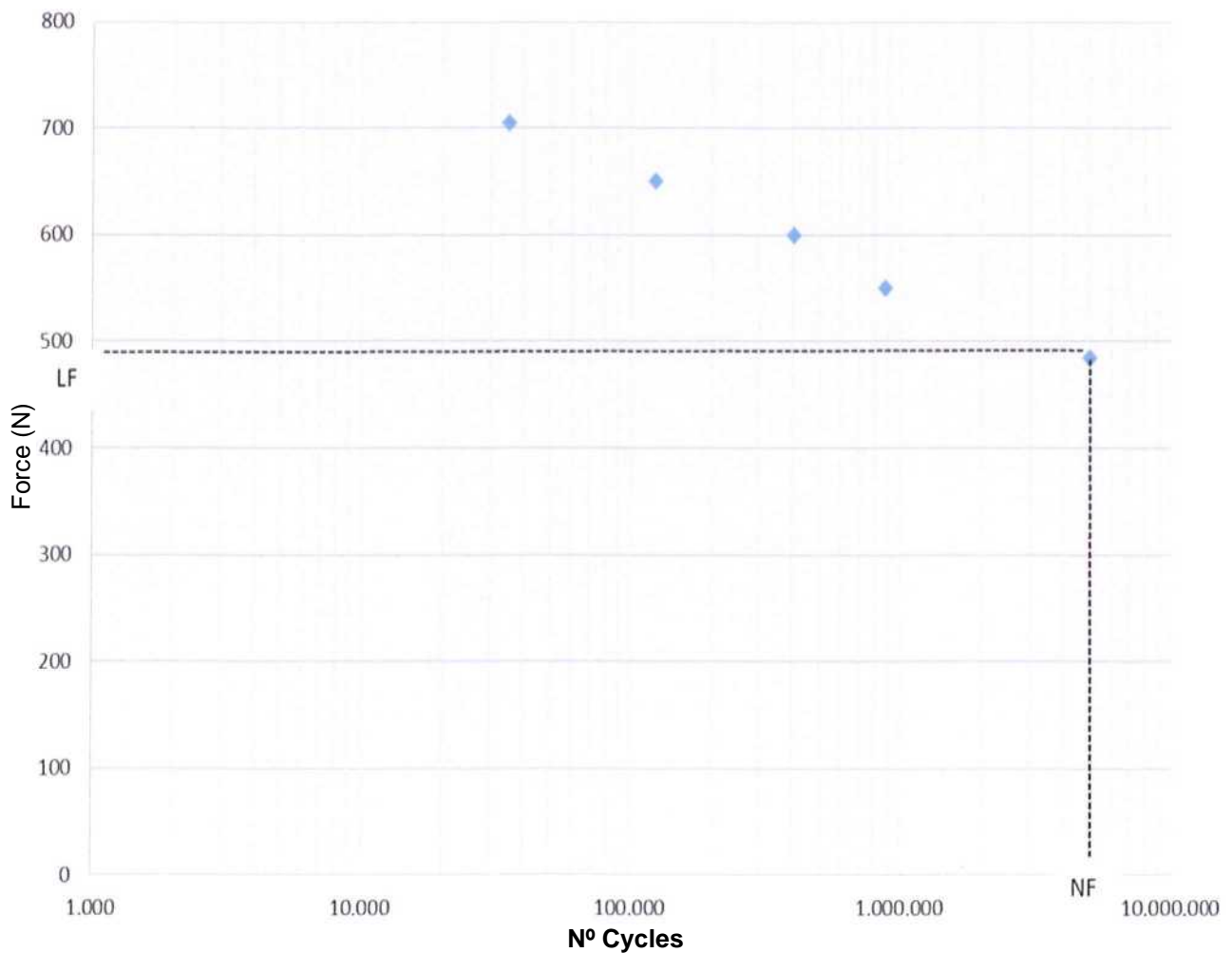
2.8. Fatigue Analysis.

Flexo-compression fatigue resistance was simulated on the whole implant-interface. Different loads were simulated on the assembly and the number of load cycles were registered until the defect occurred. The results are shown in the following diagram where the number of load cycles appear for each force applied to the assembly.

Regulation ISO 14801:2007 recommends that the first load applied to begin the process is 80% of the failure load attained in a static test. The regulation recommends applying four load levels to the system.

The curve of the load cycle is drawn to show the maximum load at which the endosseous dental implant system will resist 5×10^6 cycles.

Load level	Maximum load applied (N)	Number of cycles
1	705	35.000
2	650	122.433
3	600	402.228
4	550	877.433
5	485	5.000.000



2.9. Analysis of Results.

2.9.1. Static Resistance.

The static resistance failure of the simulated Implant-Screw-Interface setting occurred because the elastic limit of the material was reached.

The resistance in the elastic limit for the Nobel Biocare Multi-Unit Connection Regular Abutment setting was **774 N**, with the geometric position indicated in the ISO 14801:2007 standards. A value over that of 700, which had been set as the objective.

The simulated settings are used on front and back teeth. Scientific studies were found on maximum bite forces with natural teeth on a variety of materials, which obtained values between 50 and 370 N for the maximum bite force with the incisor teeth (Paphangkorakit and Osborn, 1997; Fontijn-Tekamp et al., 2000; Regalo et al., 2008), between 50 and 200 N for maximum bite force with the canine teeth (Sinn et al., 1996; Fontijn-Tekamp et al., 2000) and between 100 and 260 N for maximum bite force with the premolars (Sinn et al., 1996; Fontijn-Tekamp et al., 2000) and between 60 and 645 N for maximum bite force with molar teeth (Sinn et al., 1996; Fontijn-Tekamp et al., 1998; Pereira-Cenci et al., 2007; Regalo et al., 2008).

The simulated static resistance values far outweigh the stated load values.

2.9.2. Fatigue Resistance.

The set fatigue limit was **485 N**, with the geometrics arrangement stated in ISO 14801:2007. A clearly higher value than that of 350 N, which had been set as the objective.

The setting is used on front and back teeth. Scientific studies were found on measuring natural teeth chewing force values on various materials, which obtained peak values between 5 and 54 N for incisor and canine teeth (Gay et al., 1994; Dan et al., 2003; Kohyama et al., 2004a, 2004b, 2005; Johnsen et al., 2007; Xu et al., 2008) and peak values between 50 and 284 N for premolars and molars (Morneburg Pröschel, 2003; Kohyama et al., 2004a, 2004b; Johnsen et al., 2007). The fatigue limit obtained in fatigue resistance tests far exceeds those load values.

2.10. Conclusions

In conclusion, it may be stated that the results of the Multi-Unit connection implant-interface-screw static and fatigue simulation study are satisfactory, because the set withstood higher static load values than the chewing loads and fatigue limits obtained were also higher than the usual chewing loads, as our initial objective defined.

3. TRIAL VALIDATION

IBV/FINITE ELEMENTS COMPARATIVE VALIDATION REPORT:

3.1. Abutment – dental implant set Zimmer internal hex connection Screw-vent, with narrow abutment.

Results of static and fatigue resistance to flexo-compression.

This point in the study is intended to validate the trial system by simulation using the finite element calculation, also compared to similar trial results at the Instituto de Biomecánica de Valencia (Valencia Biomechanics Institute).

3.1.1. Introduction

This report presents the corresponding results for the flexo-compression static and fatigue simulation study, for an abutment and dental implant with a hexagonal internal Zimmer Tapered Screw-Vent model.

The report numbers for the IBV trials to validate are 080115b - PROJ08/0065_2 and 080117a - PROJ08/0065_2.

ISO 14801:2007 standard "Dentistry–Implants–Dynamic fatigue test for endosseous dental implants" was used for the report.

The trial was performed by simulating the assembly with finite element software.

The results obtained in the report are purely theoretical, because the system is simulated in an ideal environment (materials, dimensions and connections).

3.1.2. Regulations

- ISO 14801:2007 "Dental-Implants dynamic fatigue test for endosseous dental implants."
- ISO 1942 "Dental vocabulary."

3.1.3. Material Used

Components Used

Component	Reference	Description	Material	Measurements
Abutment	PZIM35	Internal hexagonal abutment	TILITE with titanium	Ø3.5mm
Screw	TZIM	Direct to Implant screw	Titanium 6Al-4V Grade5	Ø2.4mm L 0.32in
Implant	TSVB13	Zimmer Dental Screw-Vent-NP Dental Implant	Titanium 6Al-4V Grade5	Ø3.7mm L 13mm

3.1.4. Material Properties

TILITE	
Model Type	Isotropic, lineal elastic
Elastic Limit	7.92897e+008 N/m ²
Tensile Stress Limit	1.06869e+009 N/m ²
Elastic Modulus/Toughness	2.1e+011 N/m ²
Density	16,975.60 lb/m ³
Shear Modulus	7.9e+010 N/m ²
Thermal Expansion Coefficient	1.7e-005 /Kelvln

Titanium 6Al-4V Grade5	
Model Type	Isotropic, lineal elastic
Elastic Limit	7.9e+008 N/m ²
Tensile Stress Limit	8.6e+008 N/m ²
Elastic Modulus/Toughness	1.138e+011 N/m ²
Density	4430 kg/m ³
Shear Modulus	4.4e+010 N/m ²
Thermal Expansion Coefficient	9e-006 /Kelvin

3.1.5. Simulation Method

The geometric arrangement of the simulation is described in ISO 14801:2007, paragraph 5.

Figure 1 shows the geometric arrangement of the elements tested according to ISO 14801:2007.

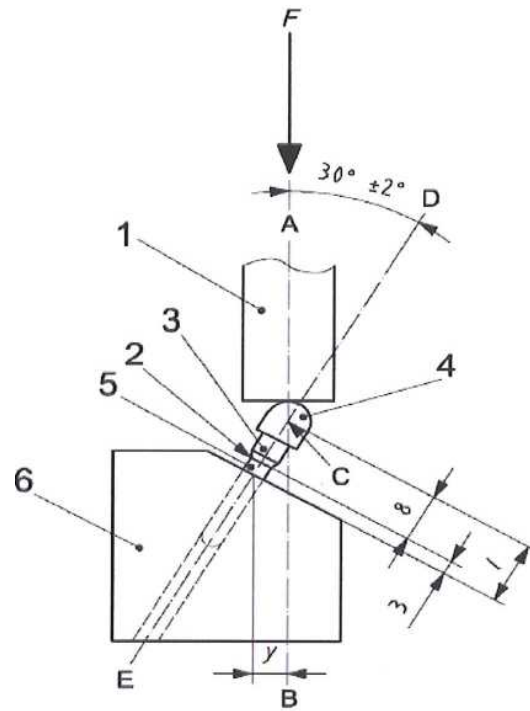


Figure 1

Heading

1. Charging device
2. Nominal bone level
3. Connection part
4. Hemispheric load member
5. Dental implant body
6. Specimen holder
- F. Loading force
- C. Loading center

The assembly of the simulation components can be seen below.

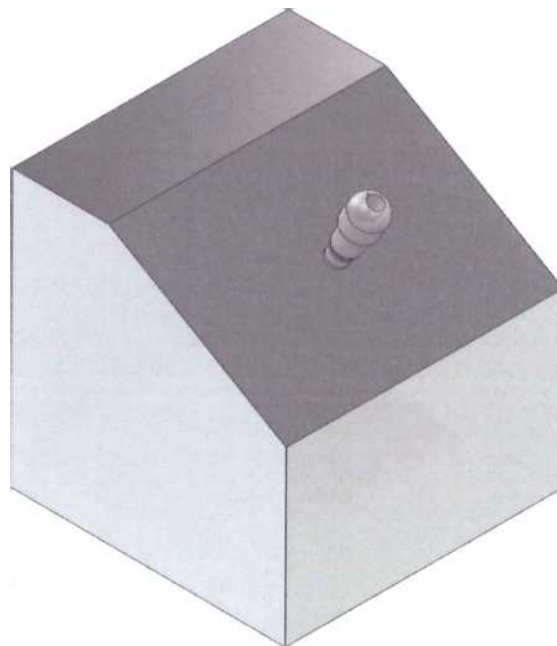


Figure 2: Isometric View

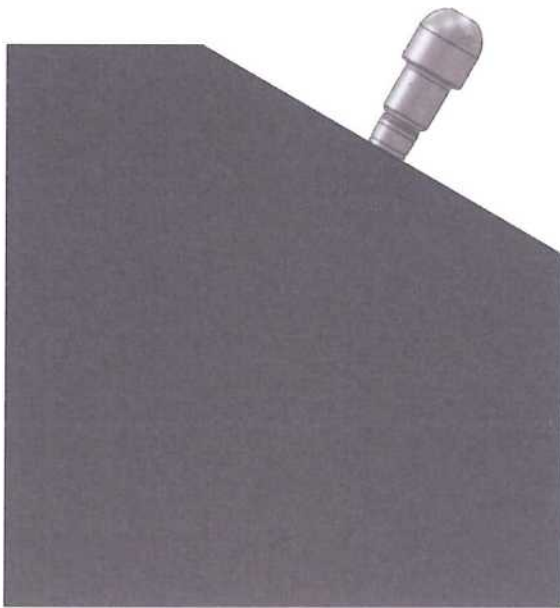


Figure 3: Solid Lateral View

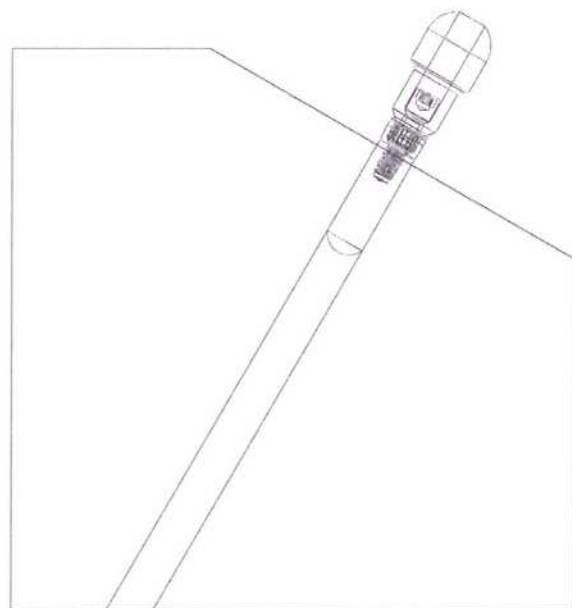


Figure 4: Lateral Wired View

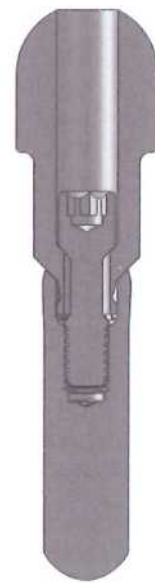
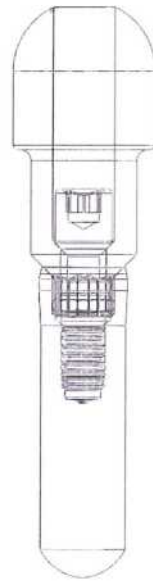


Figure 5: Implant-Pillar-Screw Assembly

3.1.6. Applied Loads

The loads applied to the assembly were developed as previously described in figure 1. Figure 6 shows the assembly with the load and the application site.

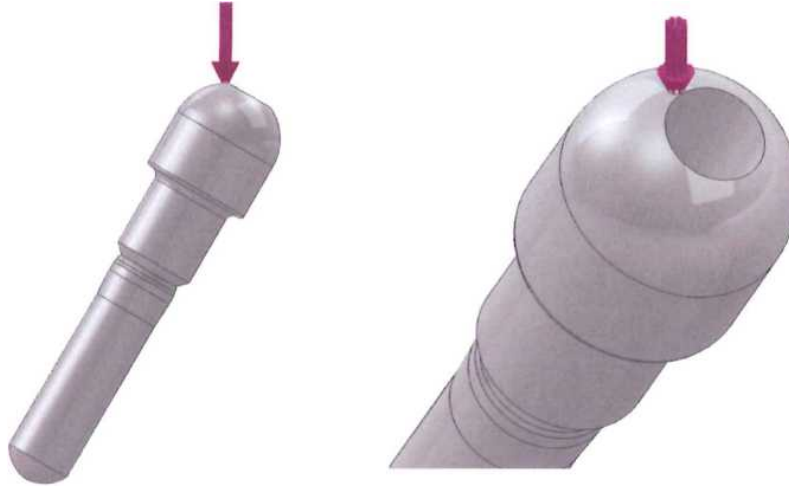


Figure 6: Load applied to the assembly

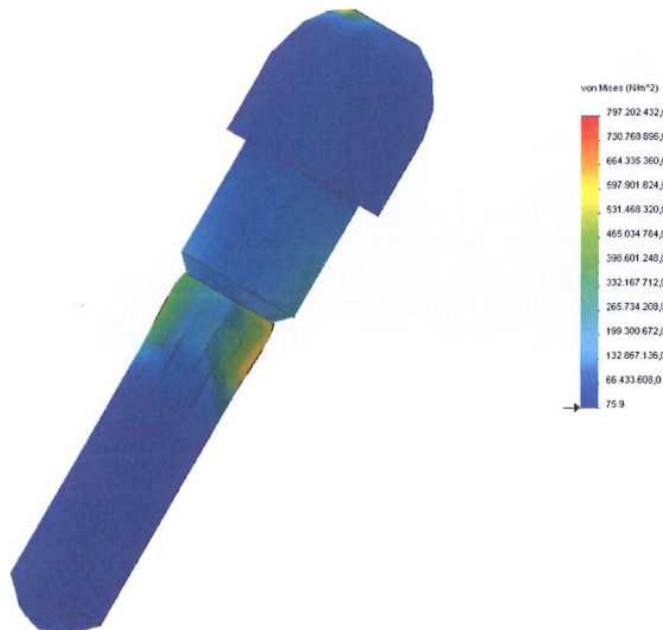
3.1.7. Static Resistance Results.

Static resistance to flexo-compression was simulated for the implant and pillar with the aim of determining the elasticity load limit and fracture load. The environmental conditions of the simulation are those stated in ISO 14801:2007.

Assembly	Yield Strength Limit (N)	Fracture Strength (N)
Zimmer Screw-Vent PN	564	603

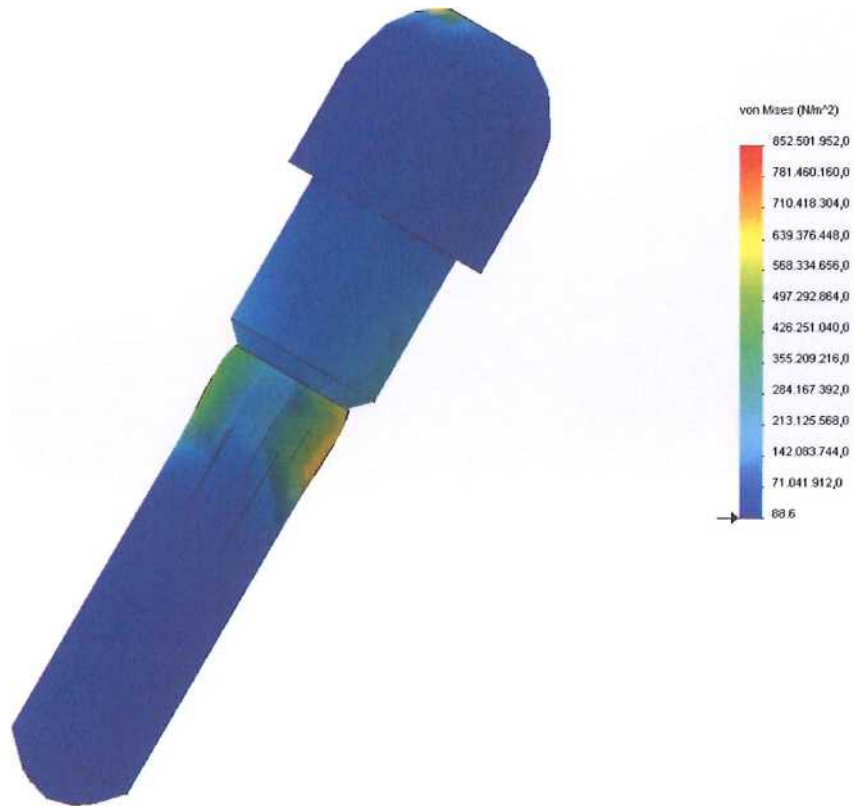
3.1.7.1. Elasticity Stress Limits.

The elastic limit of the implant is reached at **564 N**. The critical areas of the assembly are those that can be seen with a greenish and reddish tone, which is where the load is applied and the connection area between the pillar and the implant.

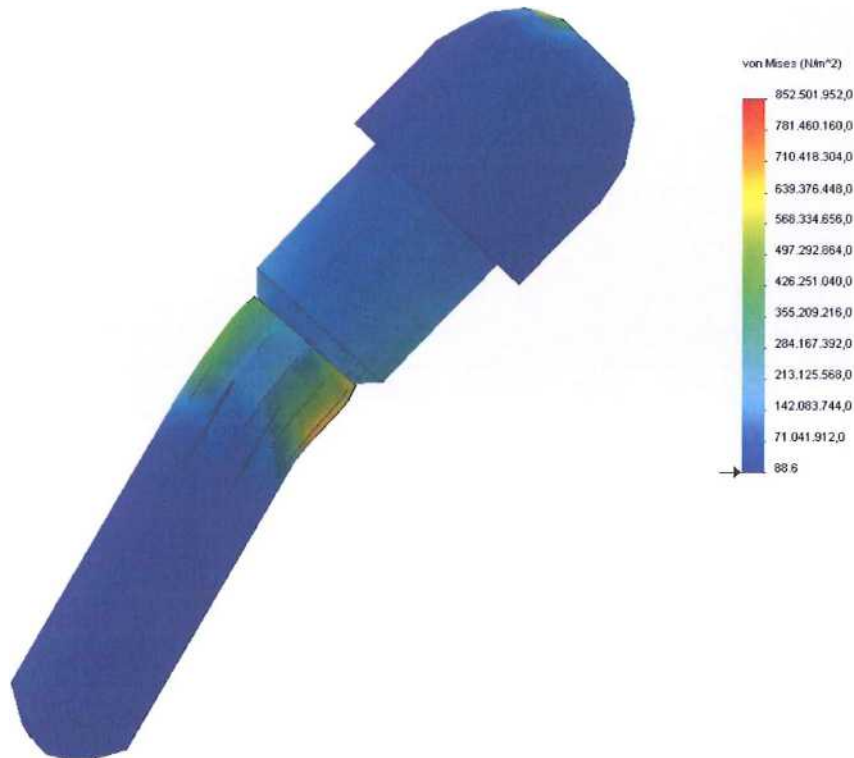


3.1.7.2. Fracture Stress.

The breaking point is reached for a **603N** load. When the load of 603N is applied the implant becomes defective and the implant breaks. The deficient area of the assembly can be seen with more precision in section 7.6 Fracture Stress Limit (Scale 20)



Fracture Stress Limit (Scale 20)



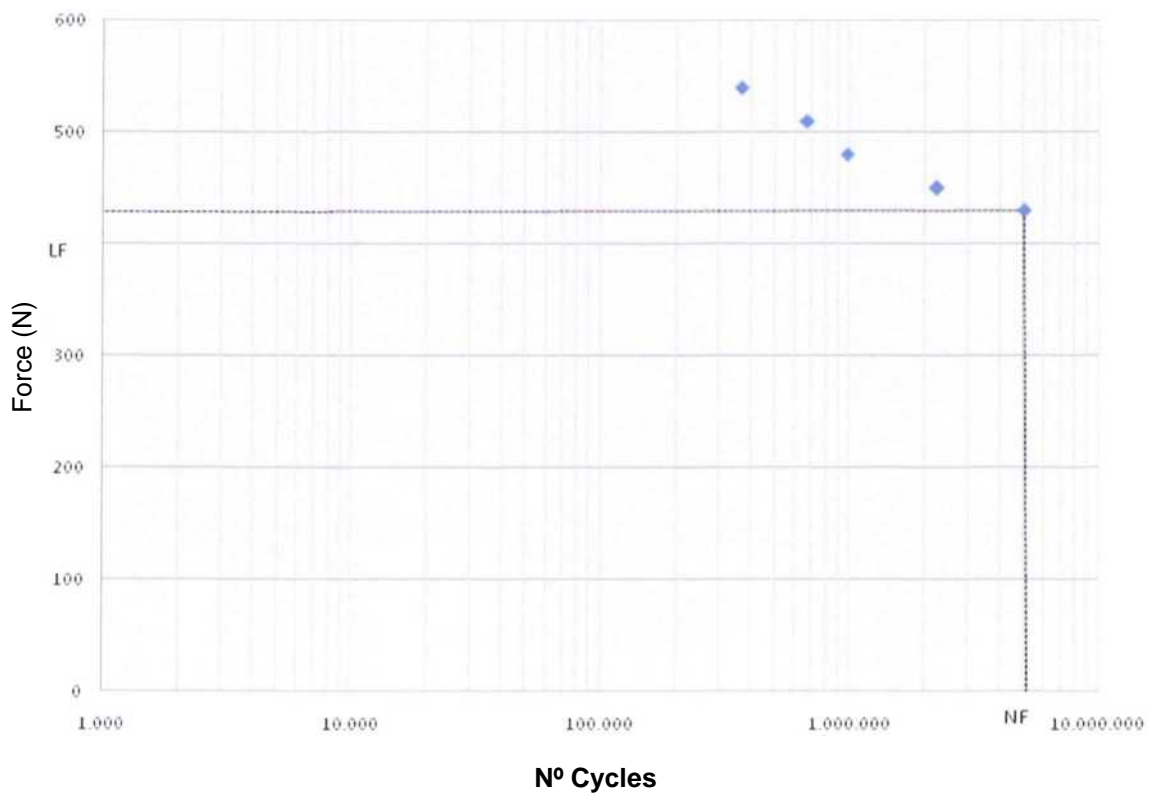
3.1.8. Fatigue Analysis.

Flexo-compression fatigue resistance was simulated on the whole implant-pillar. Different loads were simulated on the assembly and the number of load cycles were registered until the defect occurred. The results are shown in the following diagram where the number of load cycles appear for each force applied to the assembly.

Regulation ISO 14801:2007 recommends that the first load applied to begin the process is 80% of the failure load attained in a static test. The regulation recommends applying four load levels to the system.

The curve of the load cycle is drawn to show the maximum load at which the endosseous dental implant system will resist 5×10^6 cycles.

Load level	Maximum load applied (N)	Number of cycles
1	540	364.642
2	510	670.120
3	480	968.691
4	450	2.231.398
5	430	5.000.000



3.1.9. Analysis of Results.

3.1.9.1. Static Resistance.

The static resistance failure of the simulated Implant-Screw-Interface setting occurred due to reaching the elasticity limit of the material.

The elastic stress yield for the Internal Hex Connection Zimmer Brand Screw-Vent Narrow Abutment was **564 N**, with the geometric position indicated in the ISO 14801:2007 standards.

Due to the diameter value, the simulated assembly is only used only on front teeth. Scientific studies were found on maximum bite forces with natural teeth on a variety of materials, which obtained values between 50 and 370 N for the maximum bite force with the incisor teeth (Paphangkorakit and Osborn, 1997; Fontijn-Tekamp et al., 2000; Regalo et al., 2008), between 50 and 200 N for maximum bite force with the canine teeth (Sinn et al., 1996; Fontijn-Tekamp et al., 2000) and between 100 and 260 N for the maximum bite force with premolar teeth (Sinn et al., 1996; Fontijn-Tekamp et al., 2000).

The simulated static resistance values far outweigh the stated load values.

3.1.9.2. Fatigue Resistance.

The assembly fatigue limit has been 430 N, with the geometric arrangement stated in ISO 14801:2007.

The whole assembly is only used on front teeth. Scientific studies were found on measuring natural teeth chewing force values on various materials, which obtained peak values between 50 and 54 N for incisor and canine teeth (Gay et al., 1994; Dan et al., 2003; Kohyama et al., 2004a, 2004b, 2005; Johnsen et al., 2007; Xu et al., 2008) and peak values between 50 and 284 N for premolars and molars (Morneburg Pröschel, 2003; Kohyama et al., 2004a, 2004b; Johnsen et al., 2007).

The fatigue limit obtained in fatigue resistance tests far exceeds those load values.

3.1.10. Conclusions.

In conclusion it can be stated that the the static and fatigue study simulation results for the whole internal hex implant-abutment-screw connection assembly are satisfactory and and close to those obtained by the IBV in flexo-compression fatigue and static trials (as may be seen in the comparative table below), as the implant withstood values above the chewing loads and the fatigue limit obtained was higher than the normal mastication loads.

These results are sufficiently near for the validation of the use of finite elements for static and fatigue tests on the implant and abutment sets.

The intention of this study is not to stop performing real trials such as those conducted so far, but to reduce the number of trials in order to make better use of company resources.

The results are extrapolated to the different implant-abutment assemblies whenever the trials are similar to this work.

3.2. Comparative table.

Below are the comparative tables for those elements used in the tests for both cases 3.1 and 3.2 and the results obtained, compared to physical tests conducted by the Valencia Biomechanics Institute.

3.2.1. Elements on which the assay was performed

Finite Assay Elements.

Component	Reference	Description	Material	Measurements
Abutment	PZIM35	Internal hexagonal abutment	TILITE with titanium	Ø3.5mm
Screw	TZIM	Direct implant screw	Titanium 6Al-4V Grade5	Ø2.4mm L 0.32in
Implant	TSVB13	Zimmer Dental Screw-Vent-NP Dental Implant	Titanium 6Al-4V Grade5	Ø3.7mm L 13mm

IBV Trial

Component	Reference	Description	Material	Measurements
Abutment	PZIM35	Internal hexagonal abutment	TILITE with titanium	Ø3.5mm
Screw	TZIM	Direct to Implant screw	Titanium 6Al-4V Grade5 Torque of 20 Ncm.	Ø2.4mm L 0.32in
Implant	TSVB13	Zimmer Dental Papered Screw-Vent Implant with MTX surface.	Titanium alloy	Ø3.7mm L 13mm Hex. Int 2.5x1.5mm

As can be seen in both cases the elements tested are the same or complete equivalents.

3.2.2. Trial results

Assembly	Yield Strength Limit (N)	Fracture Strength (N)	Applied Fatigue Load (N)	Number of cycles
IBV Trials			463	5.000.000
according to report 080115b - PROY08/0065 2 and 080117a-PROY08/0065_2.	579	591	538*	2.650.000
			567	800.000
			430	5.000.000
Finite Elements				
according to 3.2	564	603	510	670.000
			540	364.000

3.3. VALIDATION

To validate the calculation by finite elements, system simulations and physical trials (IBV) were performed and later compared, see the results table from the previous point.

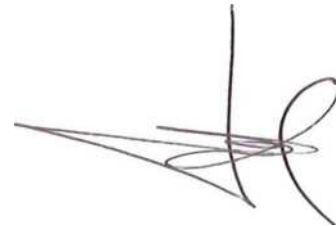
To validate a wide range of actions, the M 1.4 metric screw, within the assembly of Dynamic Interface and dental implant of Multi-Unit Connection type Nobel Biocare Brand Regular Abutment with the M 1.4 metric screw, which is the most crucial within the set of screws, was used as a starting point.

The dispersion of values in the physical trials were been taken into account, mainly due to the assembly having three or four pieces and their influence on fatigue resistance being difficult to predict, there may also be dispersion in the tightening. Usually the net stress on the screw may be 20% of the tightening stress because friction may absorb 80%.

In the case of point 3.1: Pillar set - Zimmer internal hex connection screw-vent dental implant, with narrow abutment. The dispersion found by IBV was above 50N.

Applying the dispersals found by IBV, the results are found to be entirely comparable, which is why the the finite element calculation system, both for static mechanical properties and fatigue was validated.

By validating the finite element calculation system, the results of the static and fatigue study of the screw-interface-implant Multi-Unit Connection are validated, as the assembly withstood static load values which were higher than the chewing loads and fatigue limits obtained were also higher than the normal chewing loads. Both for front and back teeth.



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From Colegio de Ingenieros Industriales
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Engineering College).

*The value of 2,650,000 cycles, which what may be difficult to compare for a load of 538N, was obtained by the average of both trials performed by IBV for this load which are 305,000 and 5,000,000 cycles.



4. References

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